UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,219	01/17/2007	Mitsuru Emi	295017US0X PCT	6918

22850 7590 06/24/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

NOTIFICATION DATE	DELIVERY MODE
06/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,219	EMI ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1 , claim(s) 1, 10-12, and 17-19, in part, drawn to a gene consisting of at least one of the following definitions correlated with prediction of the postoperative prognosis of breast cancer;1) a marker gene group capable of establishing classification of genes from breast cancer patients died within 5 years after a surgical operation (5y-D group) and genes from patients survived free of disease for several years or more after the operation (5y-S group), depending on their expression functions, in estrogen receptor-negative breast cancer,2) a marker gene group capable of establishing classification of genes from n0 breast cancer patients recurred within 5 years after an operation (5Y-R group) and genes from patients survived free of disease for 5 years or more after the operation (5Y-F group), depending on their expression functions, in (node-negative) (n0) breast cancer with no metastasis to a lymph node in the operation,3) a marker gene group capable of establishing classification of genes from breast cancer patients died within 5 years after a surgical operation (5D group) and genes from patients survived free of disease for several years or more after the operation (5S group), depending on their expression functions, in primary breast cancer.

Group 2, claim(s) 2, 10-12, and 17-19, in part, drawn to a gene selected from the following sequences correlated with prediction of the postoperative prognosis of primary breast cancer;pro-alpha-1 type 3 collagen (PIIIP),complement component Clr,dihydropyrimidinase-like 3 (DPYSL3),protein tyrosine kinase 9-like (PTK9L),carboxypeptidase E (CPE),alpha-tubulin,beta-tubulin,heat shock protein HSP 90-alpha gene,malate dehydrogenase, NADH dehydrogenase (ubiquinone) 1 beta subcomplex, 3 (NDUFB3).

Group 3, claim(s) 3, 10-12, and 17-19, in part, drawn to a gene selected from the following sequences highly expressed in a group of good prognosis correlated with prediction of the postoperative prognosis of primary breast cancer;pro-alpha-1 type 3 collagen (PIIIP),complement component Clr,dihydropyrimidinase-like 3 (DPYSL3),protein tyrosine kinase 9-like (PTK9L),carboxypeptidase E (CPE),alpha-tubulin,beta-tubulin.

Group 4, claim(s) 4, 10-12, and 17-19, in part, drawn a gene selected from the following sequences highly expressed in a group of bad prognosis correlated with prediction of the

postoperative prognosis of primary breast cancer; heat shock protein HSP 90-alpha gene,malate dehydrogenase,NADH dehydrogenase (ubiquinone) 1 beta subcomplex, 3 (NDUFB3).

Group 5, claim(s) 5, 10-12, and 17-19, in part, drawn a gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node in operation;AF058701/DNA polymerase zeta catalytic subunit (REV3),AM066764/lectin, galactoside-binding, soluble, 1 (galectin 1),x15940/ribosomal protein L31.,Hs.94653/neurochondrin (KIAA0607),M13436/ovarian beta-A-inhibin,Hs.5002/copper chaperone for superoxide dismutase; CCS,D67025/proteasome (prosome, macropain) 26S subunit, non-ATPase, 3,M80469/MHC class I HLA-J gene,Hs.4864/ESTs,Hs.106326/ESTs.

Group 6, claim(s) 6, 10-12, and 17-19, in part, drawn A gene selected from the following sequences highly expressed in a group of bad prognosis correlated with prediction of the postoperative prognosis, in (node-negative) (n0) breast cancer with no metastasis to a lymph node in operation;AF058701/DNA polymerase zeta catalytic subunit (REV3),AM066764/lectin, galactoside-binding, soluble, 1 (galectin 1),x15940/ribosomal protein L31.

Group 7, claim(s) 7, 10-12, and 17-19, in part, drawn A gene selected from the following sequences highly expressed in a group of good prognosis correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node in operation;Hs.94653/neurochondrin (KIAA0607),M13436/ovarian beta-A-inhibin,Hs.5002/copper chaperone for superoxide dismutase; CCS,D67025/proteasome (prosome, macropain) 26S subunit, non-ATPase, 3,M80469/MHC class I HLA-J gene,Hs.4864/ESTs,Hs.106326/ESTs.

Group 8, claim(s) 8-12, and 17-19, in part, drawn a gene selected from the following sequences correlated with prediction of the postoperative prognosis, in estrogen receptor-negative breast cancer;Hs.108504/FLJ20113/ubiquitin-specific protease otubain 1Hs.146550/MYH9/myosin, heavy polypeptide 9, non-muscleHs.194691/RAI3/retinoic acid induced 3Hs. 1975/TDRD3/tudor domain containing Hs.203952/TRRAP/transformation/transcription domain-associated proteinHs.278607/GSA7/ubiquitin activating enzyme E1-like proteinHs.429/ATP5G3/ATP synthase, H+ transporting, mitochondrialF0complex, subunitc (subunit9) isoform3Hs.75305/AIP/aryl hydrocarbon receptor interacting proteinHs.81170/PIM1/pim-1 oncogeneHs.99987/ERCC2/excision repair cross-complementing rodent repair deficiency, complementation group 2Y12781/Transducin (beta) like 1 proteinHs.104417/KIAA1205 proteincl.21783/Hypothetical proteinHs.112628/Hypothetical protein: MGC43581Hs.170345/Hypothetical protein FLJ13710Hs.53996/weakly similar to zinc finger protein 135Hs.55422/Hypothetical proteinHs.112718/ESTHs.115880/ESTHs.126495/EST.

Group 9 claim(s) 13 and 14 drawn to a method of inspecting the postoperative prognosis of breast cancer using as a marker the gene and/or probe according to any one of claims 1 to 10 or using the microarray according to claim 11 or 12.

Group 10 claim(s) 15 and 16 drawn to a method of screening cancer therapeutic medicines for controlling the postoperative prognosis of breast cancer using as a marker the gene and/or probe according to any one of claims 1 to 10 or using the microarray according to claim 11 or 12.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-10 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking Groups 1-10 appears to be a gene selected from the following sequences correlated with prediction of the postoperative prognosis of primary breast cancer. However, Chu *et al.* (Journal of Biological Chemistry, Vol. 260, No. 7, pages 4357-4363, 1985, IDS) teach pro-alpha-1 type 3 collagen, see Abstract, see Abstact, p. 4357. Therefore, the technical feature linking the inventions of Groups 1-10 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Species Elections for Group 1

A. Claims 1, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene correlated with prediction of the postoperative prognosis of breast cancer:

1) a marker gene group capable of establishing classification of genes from breast cancer patients died within 5 years after a surgical operation (5y-D group) and genes from patients survived free of disease for several years or more after the operation (5y-S group), depending on their expression functions, in estrogen receptor-negative breast cancer,

2) a marker gene group capable of establishing classification of genes from n0 breast cancer patients recurred within 5 years after an operation (5Y-R group) and genes from patients survived free of disease for 5 years or more after the operation (5Y-F group), depending on their expression functions, in (node-negative) (n0) breast cancer with no metastasis to a lymph node in the operation,

3) a marker gene group capable of establishing classification of genes from breast cancer patients died within 5 years after a surgical operation (5D group) and genes from patients survived free of disease for several years or more after the operation (5S group), depending on their expression functions, in primary breast cancer.

Upon election of a species group above, Applicants must identify the gene members of the marker gene group from the genes disclosed in the specification (Tables, 2, 5, 6, 11, and 12) and claims 2-8.

Species Elections for Group 2

A. Claims 2, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

pro-alpha-1 type 3 collagen (PIIIP),complement component Clr,dihydropyrimidinase-like 3 (DPYSL3),protein tyrosine kinase 9-like (PTK9L),carboxypeptidase E (CPE),alpha-tubulin,beta-tubulin,heat shock protein HSP 90-alpha gene,malate dehydrogenase,NADH dehydrogenase (ubiquinone) 1 beta subcomplex, 3 (NDUFB3).

Species Elections for Group 3

A. Claims 3, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

pro-alpha-1 type 3 collagen (PIIIP),complement component Clr,dihydropyrimidinase-like 3 (DPYSL3),protein tyrosine kinase 9-like (PTK9L),carboxypeptidase E (CPE),alpha-tubulin,beta-tubulin.

Species Elections for Group 4

A. Claims 4, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

heat shock protein HSP 90-alpha gene, malate dehydrogenase,NADH dehydrogenase (ubiquinone) 1 beta subcomplex, 3 (NDUFB3).

Species Elections for Group 5

A. Claims 5, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

AF058701/DNA polymerase zeta catalytic subunit (REV3),AM066764/lectin, galactoside-binding, soluble, 1 (galectin 1),x15940/ribosomal protein L31.,Hs.94653/neurochondrin (KIAA0607),M13436/ovarian beta-A-inhibin,Hs.5002/copper chaperone for superoxide dismutase; CCS,D67025/proteasome (prosome, macropain) 26S subunit, non-ATPase, 3,M80469/MHC class I HLA-J gene,Hs.4864/ESTs,Hs.106326/ESTs.

Species Elections for Group 6

A. Claims 6, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

AF058701/DNA polymerase zeta catalytic subunit (REV3),AM066764/lectin, galactoside-binding, soluble, 1 (galectin 1),x15940/ribosomal protein L31.

Species Elections for Group 7

A. Claims 7, 10-12, and 17-19 are generic to the following disclosed patentably distinct species of gene correlated with prediction of the postoperative prognosis of breast cancer:

Hs.94653/neurochondrin (KIAA0607),M13436/ovarian beta-A-inhibin,Hs.5002/copper chaperone for superoxide dismutase; CCS,D67025/proteasome (prosome, macropain)

26S subunit, non-ATPase, 3,M80469/MHC class I HLA-J gene, Hs.4864/ESTs, Hs.106326/ESTs.

Species Elections for Group 8

A. Claims 8-12, and 17-19 are generic to the following disclosed patentably distinct species of gene/probe correlated with prediction of the postoperative prognosis of breast cancer:

Hs.108504/FLJ20113/ubiquitin-specific protease otubain 1Hs.146550/MYH9/myosin, heavy polypeptide 9, non-muscleHs.194691/RAI3/retinoic acid induced 3Hs. 1975/TDRD3/tudor domain containing Hs.203952/TRRAP/transformation/transcription domain-associated proteinHs.278607/GSA7/ubiquitin activating enzyme E1-like proteinHs.429/ATP5G3/ATP synthase, H+ transporting, mitochondrialF0complex, subunitc (subunit9) isoform3Hs.75305/AIP/aryl hydrocarbon receptor interacting proteinHs.81170/PIM1/pim-1 oncogeneHs.99987/ERCC2/excision repair cross-complementing rodent repair deficiency, complementation group 2Y12781/Transducin (beta) like 1 proteinHs.104417/KIAA1205 proteincl.21783/Hypothetical proteinHs.112628/Hypothetical protein: MGC43581Hs.170345/Hypothetical protein FLJ13710Hs.53996/weakly similar to zinc finger protein 135Hs.55422/Hypothetical proteinHs.112718/ESTHs.115880/ESTHs.126495/EST.

Species Elections for Group 9

A. Claims 13 and 14 are generic to the following disclosed patentably distinct species of marker gene and/or probe: The genes disclosed in the specification (Tables, 2, 5, 6, 11, and 12) and claims 2-8. Applicants must identify a specific marker gene and/or probe.

Species Elections for Group 10

A. Claims 15 and 16 are generic to the following disclosed patentably distinct species of marker gene and/or probe: The genes disclosed in the specification (Tables 2, 5, 6, 11, 12) and claims 2-8. Applicants must identify a specific marker gene and/or probe.

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Peter J Reddig/
Examiner, Art Unit 1642